UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,874	09/30/2003	Howard Bernstein	17976-0006	6790

29052 7590 01/05/2010

SUTHERLAND ASBILL & BRENNAN LLP
999 PEACHTREE STREET, N.E.
ATLANTA, GA 30309

EXAMINER	
SOROUSH, ALI	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
01/05/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/675,874	BERNSTEIN ET AL.	
	Examiner	Art Unit	
	ALI SOROUSH	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-26 and 28-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-26 and 28-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09182009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt

Applicant's response filed on 09/18/2009 to the Office Action mailed on 03/20/2009 is acknowledged.

Status of the Claims

Claims 1, 3, 9, 31, 32, 33, 46, and 50 are currently amended and claims 13 and 27 are cancelled. Therefore, claims 1-12 14-26 and 28-56 are currently pending examination for patentability.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1. Claims 1-10, 14-21, 25, 26, and 31-53 are rejected under 35 U.S.C. 102(a) as being anticipated by Tarara et al. (International Patent Application Published Under the PCT WO 99/16419, Published 04/08/1999).

Weers et al. teach, “Engineered particles are provided for the delivery of a bioactive agent to the respiratory tract of a patient. The particles may be used in the form of dry powders or in the form of stabilized dispersions comprising a nonaqeous continuous phase. In particularly preferred embodiments the particles may be used in conjunction with an inhalation device such as powder inhaler, metered dose inhaler or a nebulizer.” (See abstract). The perforated microstructures comprise at least one bioactive agent, have a geometric diameter between 0.5 and 5 microns. (See page 66, claim 1 and claim 9). The microstructure comprise a surfactant which is preferably a phospholipid. (See page 10, Lines 27-35 and page 11, Lines 1-14). The bioactive agent is selected from the group consisting of antiallergis, bronchodilators, antibiotics, antineoplastics, steroids, proteins, peptides, and combinations thereof. (See page 14, Lines 8-20). In a preferred embodiment hollow porous particles of beclomethasone dipropionate (BDP) are prepared by forming an emulsion comprising 74 mg of BDP, 500mg of egg phosphotidylcholine, 7 mg of polaxmer and 15 mg of sodium oleate in methanol and spray drying the emulsion to form free flowing white powder of BDP particles. (See page 55, Lines 12-27). In another preferred embodiment the hollow porous particles of beclomethasone dipropionate (BDP) are loaded into a dry powder inhalation device, wherein the mean particle size was determined to be 1.2μm and 95% were under 2.2μm. (See page 62, Lines 1-32). The structural matrix can further comprise synthetic or natural polymers such as polylactides and polylactide-co-glycolides to tailor the delivery profile of respitory dispersion to optimize the effectiveness of the bioactive agent. (See page 12, Lines 19-29). Additional excipients

may be added to the aerosol formulation to improve drug delivery and deposition, shelf-life and patient acceptance, such excipients include mannitol, sorbitol, lactose, and trehalose. (See page 13, Lines 3-12). With regard to the instantly claimed limitations on the duration of the drug release (2 to 24 hours), it is the Examiners position that since the formulation of Weers et al. is structurally indistinguishable from the instant claims the formulation of Weers et al. would inherently have the same release profile. For the forgoing reasons the instant claims are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 11, 12, 22-24, 28-30, and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarara et al. (International Patent Application Published Under the PCT WO 99/16419, Published 04/08/1999).

Applicant Claims

Applicant claims a sustained release pharmaceutical formulation for delivery comprising a porous microparticle comprising a pharmaceutical agent dispersed in a hydrophobic matrix of polylactide or polylactide-co-gylcolide and further comprising a bulking agent.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Tarara et al. are discussed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Tara et al. does teach a preferred embodied composition which comprises polactide or polylactide-co-glycolide and further comprising a bulking agent. Tarara et al. does make such a composition obvious.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to add polylactide or polylactide-co-glycolide and one of mannitol, sorbitol, lactose, and trehalose. One would have been motivated to so Tarara et al. teach that one could either a synthetic polymer in order to optimize the effectiveness of the bioactive agent. Tarara et al further teach that the addition of mannitol, sorbitol, lactose, or trehalose is useful to improve drug delivery and deposition, shelf-life and patient acceptance. For the foregoing reasons the

instant invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
Art Unit: 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616